K012189

MAR 5 2002

15.0 PREMARKET NOTIFICATION [510(K)] SUMMARY

15.1 Name, Address and Phone numbers of Manufacturer

- **Name of Submitter**

Mr. Ashit B. Shah	
Director	**Signature**

- **Registered address and address of manufacturing and sterilization plant**

ANGIPLAST PRIVATE LIMITED
4803, Phase-IV, G.I.D.C. Estate,
Vatva, Ahmedabad 382 445
India
Phone No.: +91 79 584 0661 / 584 1967
Fax No.: +91 79 584 1009
E-mail: medical.appl@gems.vsnl.net.in

- **Date:** 18-6-2001

15.2 Details of legally marketed device to which we claim equivalence

1. Name & Description : PRIMARY I.V. SET, Convertible Pin, 100 Inch with Backcheck Valve and 2 CLAVE® ports Piggyback MICRODRIP® with OPTION-LOK®

   Trade Name : LifeShield®

   Name & Address of Manufacturer : Abbott Laboratories, North Chicago, IL 60064, USA

2. Name & Description : Continu-Flo® Solution Set

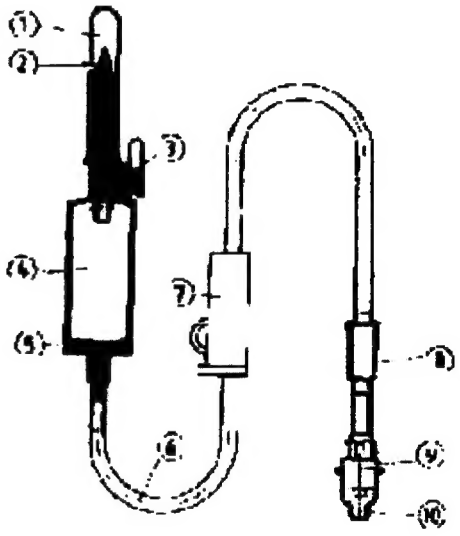
   Trade Name : Interlink® System

   Name & Address of Manufacturer : Baxter Healtchcare Corporation, Deerfield, IL 60015 USA

15.3 Description of the Device

- The product is Single Use Sterile Infusion Set for Medical Use.

The infusion set consists of the components as illustrated in figure given below.



Legend		
ABS	:	Acrylonitrile Butadene Styrene
HDPE	:	High-Density Polyethylene
LDPE	:	Low-Density Polyethylene
PVC	:	Polyvinyl Chloride
PP	:	Polypropylene

No	Item	Intended Use	Material
1	Protective cap of the closure-piercing device (Spike Guard)	To protect point of closure-piercing device from damage and to maintain sterility of interior of infusion set	PP
2	Closure-piercing device (Spike)	To insert in stopper of bottles or plastic container of large volume parenteral solution	ABS
3	Air vent filter assembly with closure	To admit air and to prevent the ingress of microorganisms into the bottle / plastic container during infusion	PVC and PP
4	Drip Chamber	Drip-chamber to assist the procedure of priming and continuous observation of fall of drops.	PVC

5	Fluid filter	To filter parenteral solution	HDPE
6	Tubing	To transfer the parenteral solution from bottle / plastic container to patient	PVC using DEHP plasticizer
7	Flow regulator	To control flow of infusion of parenteral solution	PP, HDPE
8	Injection site	To administer extra medicament during infusion	Latex
9	Male fitting (Adaptor)	To connect with female fitting used to infuse parenteral solution	HDPE
10	Protective cap of the male fitting	To protect end of male fitting and to maintain sterility of interior of infusion set	LDPE

15.4 Intended use of the Medical Device:

To administer parenteral fluids / medication into the patient's intravascular system.

15.5 Summary of the technical characteristics of our device compared to legally marketed devices (two American brands)

1. Summary of comparative technical characteristics

   From the comparison it is observed that our product is found to be substantially equivalent to Two similar American Products. The two American brands as well as our brand comply with the requirements of ISO 8536-4 in all critical requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 5 2002

Mr. Ashit B. Shah
Director
Angiplast Private Limited
4803, Phase IV, G. I. D. C.,
Vatva
Ahmedabad,
INDIA

Re: K012189
Trade/Device Name: Angeltouch Vented IV Adminstration Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: January 11, 2002
Received: January 15, 2002

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012189

Angiplast Pvt. Ltd., Ahmedabad, India	Issue No. 1 Date: January 1, 2001
Device Master File - 510(k)	Revision No. 3 Date: February 20, 2002
I.V. ADMINISTRATION SET	

12.0 STATEMENT OF INDICATIONS FOR USE

To administer parenteral fluids / medication into the patient's vascular system.

The sterile I.V. Administration Set is indicated for use to administrater parenteral fluids / medication into the patients vascular system.

Patricia Cucente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012189

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12.0	1 of 1	A. D. PATEL	S. Y. SHAH